K000085

MAR 17 2000

510(k) Summary of Safety and Effectiveness

The following section is included as required by the Safe Medical Device Act (SMDA) of 1990.

Name: Portsett, Inc.
Address: 7 Coralwind
Aliso Viejo, CA 92656
CONTACT PERSON: Salvadore F. Palomares, RAC
PHONE NUMBER: (949) 463-6146
Fax Number (949) 498-9601

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:
Trade Name: Portsett
Common Name: Hypodermic Single Lumen Needle/Accessory
Classification Name: Same

Equivalent Device: BPOS-IVAD Stabilizer (SE-K983480)

Device Description:
The Portsett is available in both a non-sterile, as well as, a sterile, non-pyrogenic, single use formats intended for use as an accessory to hypodermic single lumen needles.

The Portsett is used to stabilize the injection site just prior to inserting the needle or removing it from an implantable intravascular access device. In addition, the Portsett has a needle port to hold the extracted needle until it is disposed of per facility protocol. The Portsett is similar in shape and size to a small flat disk/spoon with a narrow slot running from the top edge to the center of the disk/spoon.

The Portsett can be used to assist in the insertion and extraction of non-coring "Huber" type and straight needles (19 – 24 G.) with needle lengths ranging from ¼ to 2". The Portsett can be used with implanted ports.

Intended Use:
The Portsett is a device intended to assist in stabilizing the area of skin over the site of an implanted vascular access device. With the area stabilized, a needle can be inserted into or removed from the implanted vascular access device without direct contact between the user's hands and the intravascular access device site.

Biocompatibility:
The materials used to manufacture the Portsett are used in legally marketed devices under comparable conditions of use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2000

Portsett, Incorporated
C/O Salvadore F. Palomares, RAC
Consultant
154 Via Lampara
Rancho Santa Margarita, California 92688

Re: K000085
Trade Name: Porsett
Regulatory Class: II
Product Code: FMI
Dated: January 9, 2000
Received: January 12, 2000

Dear Mr. Palomares:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4690. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k): K000085

Device Name: **Portsett**

Indications for Use: The Portsett is a device intended to assist in stabilizing the area of skin over the site of an implanted vascular access device. With the area stabilized, a needle can be inserted into or removed from the implanted vascular access device without direct contact between the user's hands and the intravascular access device site.

Concurrence of CDRN, Office of Device Evaluation (ODE)

Prescription Use ___✓___ or Over the Counter Use
(Per 21 CNR 801.109)

Patricia Cucente
(Division Sign-Off)
Division of Dental, Infection Control, and
General Hospital Devices
510(k) Number K000085